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subject firm shall be deemed to know what it would have known if it had exercised due care to ascertain the truth of complaints or other representations. This includes the knowledge a firm would have if it conducted a reasonably expeditious investigation in order to evaluate the reportability of a death or grievous bodily injury or other information. (See § 1115.14.)

§ 1115.12 Information which should be reported; evaluating substantial product hazard.

(a) *General.* Subject firms should not delay reporting in order to determine to a certainty the existence of a reportable noncompliance, defect or unreasonable risk. The obligation to report arises upon receipt of information from which one could reasonably conclude the existence of a reportable noncompliance, defect which could create a substantial product hazard, or unreasonable risk of serious injury or death. Thus, an obligation to report may arise when a subject firm received the first information regarding a potential hazard, noncompliance or risk. (See § 1115.14(c).) A subject firm in its report to the Commission need not admit, or may specifically deny, that the information it submits reasonably supports the conclusion that its consumer product is noncomplying, contains a defect which could create a substantial product hazard within the meaning of section 15(b) of the CPSA, or creates an unreasonable risk of serious injury or death. After receiving the report, the staff may conduct further investigation and will preliminarily determine whether the product reported upon presents a substantial product hazard. This determination can be based on information supplied by a subject firm or from any other source. If the matter is adjudicated, the Commission will ultimately make the decision as to substantial product hazard or will seek to have a court make the decision as to imminent product hazard.

(b) *Failure to comply.* A subject firm must report information indicating that a consumer product which it has distributed in commerce does not comply with an applicable consumer product safety standard or ban issued under the CPSA, or a voluntary consumer

product safety standard upon which the Commission has relied under section 9 of the CPSA.

(c) *Unreasonable risk of serious injury or death.* A subject firm must report when it obtains information indicating that a consumer product which it has distributed in commerce creates an unreasonable risk of serious injury or death.

(d) *Death or grievous bodily injury.* Information indicating that a noncompliance or a defect in a consumer product has caused, may have caused, or contributed to the causing, or could cause or contribute to the causing of a death or grievous bodily injury (e.g., mutilation, amputation/dismemberment, disfigurement, loss of important bodily functions, debilitating internal disorders, severe burns, severe electrical shocks, and injuries likely to require extended hospitalization) must be reported, unless the subject firm has investigated and determined that the information is not reportable.

(e) *Other information indicating a defect or noncompliance.* Even if there are no reports of a potential for or an actual death or grievous bodily injury, other information may indicate a reportable defect or noncompliance. In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to know what a reasonable and prudent manufacturer (including an importer), distributor, or retailer would know. (See § 1115.11.)

(f) *Information which should be studied and evaluated.* Paragraphs (f)(1) through (7) of this section are examples of information which a subject firm should study and evaluate in order to determine whether it is obligated to report under section 15(b) of the CPSA. Such information may include information that a firm has obtained, or reasonably should have obtained in accordance with § 1115.11, about product use, experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States. All information should be evaluated to determine whether it suggests the existence of a noncompliance, a defect, or an unreasonable risk of serious injury or death:

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(1) Information about engineering, quality control, or production data.

(2) Information about safety-related production or design change(s).

(3) Product liability suits and/or claims for personal injury or damage.

(4) Information from an independent testing laboratory.

(5) Complaints from a consumer or consumer group.

(6) Information received from the Commission or other governmental agency.

(7) Information received from other firms, including requests to return a product or for replacement or credit. This includes both requests made by distributors and retailers to the manufacturer and requests from the manufacturer that products be returned.

(g) *Evaluating substantial risk of injury.* Information which should be or has been reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect or noncompliance exists and whether it results in a substantial risk of injury to the public. In deciding whether to report, subject firms may be guided by the following criteria the staff and the Commission use in determining whether a substantial product hazard exists:

(1) *Hazard created by defect.* Section 15(a)(2) of the CPSA lists factors to be considered in determining whether a defect creates a substantial risk of injury. These factors are set forth in the disjunctive. Therefore, the existence of any one of the factors could create a substantial product hazard. The Commission and the staff will consider some or all of the following factors, as appropriate, in determining the substantiality of a hazard created by a product defect:

(i) *Pattern of defect.* The Commission and the staff will consider whether the defect arises from the design, composition, contents, construction, finish, packaging, warnings, or instructions of the product or from some other cause and will consider the conditions under which the defect manifests itself.

(ii) *Number of defective products distributed in commerce.* Even one defective product can present a substantial risk

of injury and provide a basis for a substantial product hazard determination under section 15 of the CPSA if the injury which might occur is serious and/or if the injury is likely to occur. However, a few defective products with no potential for causing serious injury and little likelihood of injuring even in a minor way will not ordinarily provide a proper basis for a substantial product hazard determination. The Commission also recognizes that the number of products remaining with consumers is a relevant consideration.

(iii) *Severity of the risk.* A risk is severe if the injury which might occur is serious and/or if the injury is likely to occur. In considering the likelihood of any injury the Commission and the staff will consider the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (e.g., children, elderly, handicapped).

(iv) *Other considerations.* The Commission and the staff will consider all other relevant factors.

(2) *Hazard presented by noncompliance.* Section 15(a)(1) of the CPSA states that a substantial product hazard exists when a failure to comply with an applicable consumer product safety rule creates a substantial risk of injury to the public. Therefore, the Commission and staff will consider whether the noncompliance is likely to result in injury when determining whether the noncompliance creates a substantial product hazard. As appropriate, the Commission and staff may consider some or all of the factors set forth in paragraph (f)(1) of this section in reaching the substantial product hazard determination.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992; 66 FR 54925, Oct. 31, 2001; 71 FR 42031, July 25, 2006]

§ 1115.13 Content and form of reports; delegations of authority.

(a) *Written reports.* The chief executive officer of the subject firm should sign any written reports to the Commission under section 15(b) of the CPSA unless this responsibility has